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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,468	07/10/2000	Morten Sloth Weidner	04590461P	9245

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/613,468	Applicant(s) WEIDNER, MORTEN SLOTH	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- Th MAILING DATE of this communication app ars on th cover sh t with the corr spond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,17 and 18* is/are pending in the application.

4a) Of the above claim(s) *10-16 and 19-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-9 and 17-18 are included in the prosecution of this application.

Applicant's election of the pharmaceutical composition and method of treating hypersensitivity or inflammation are acknowledged. Preliminary Amendments of 7/10/00 are acknowledged. Claims 10-16 and19-25 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment of hypersensitivity", does not reasonably provide enablement for "prevention of hypersensitivity". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability if the art, and the working examples. All the factors

have been considered with regard to the claim, with the most relevant factors discussed below.

Nature of the Invention: All rejected claims are drawn to the method of treating or preventing hypersensitivity in a subject with the administration of the instant composition. The nature of the invention is extremely complex in that it encompasses anticipating inflammation, the location of the inflammation, and subsequently administering instant composition such that the subject treated does not trigger immune response or manifest symptoms of inflammation.

Breadth of Claims: The complex nature of the claims is greatly exacerbated by the breadth of the claims. The claim encompasses prevention of a complex autoimmune response in which all immune responses to foreign antigens are prevented since inflammation has other potential causes other than allergic reactions (i.e. infection). This may or may not be addressed by the administration of the composition.

State of the Art: The state of the art does not recognize the administration of topical or systemic compositions to prevent autoimmune responses due to inflammation. The state of the art recognizes the treatment of the symptoms of inflammation or hypersensitivity but not the cure of the disease.

Guidance of the Specification: The guidance given by the specification on how to anticipate inflammation or hypersensitivity and its location to prevent the disease is absent.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to completely envisioning/anticipating inflammation or

hypersensitivity and preventing inflammation/hypersensitivity in a human subject with the administration of the instant composition makes practicing the claimed invention unpredictable in terms of the prevention of the disease.

The Amount of Experimentation Necessary: In order to practice claimed invention, one of ordinary skill in the art would have to first to anticipate inflammation or hypersensitivity, its location, the effective dosage, duration of treatment, etc. to determine whether or not the instant composition prevents the disease. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art, one of ordinary skill in the art would have to either envision a modification of the variable factors or envision an entirely new combination of the factors, and test the invention again. If unsuccessful again, the whole process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention.

For these reasons the claim is rejected under 35 U.S.C. 112, first paragraph.

Again applicant is advised that when amendments are made, to avoid adding new matter.

Claims 1-9, 17, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent

protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1-3 recite the broad recitation of "triterpenes may be in the form of free alcohols or esters thereof", and the claims also recite "especially cinnamic acid, acetic acid or fatty acid esters" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-9, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Zabotto et al (4661343).

Zabotto et al disclose a cosmetic preparation containing karite oil from the tree Butyrospermum Parkii. The karite extract contains lupeol, stigmasterol, amyrin, and butyrospermol (Note col. 1, line 58 to col. 2, line 62). The composition is in the form of

an emulsion and is topically administered (Note examples). The reference teaches all instant amounts. Zabotto et al disclose that karate oil is known for its protecting and softening effect on the skin. Further, karite oil is known to protect the skin against erythema. (Note col. 1, lines 41-50)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zabotto et al cited above, in view of Journal of Pharmacology.

As set forth, Zabotto et al teach karite oil in a topical preparation.

Zabotto et al do not teach the application of karate oil on mucous membranes.

Journal of Pharmacology teaches the seed of Butyrospermum parkii yields shea butter, which is known for relieving inflammation in the nostrils. (Note abstract)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply Zabotto et al's karite composition to mucous membranes since the Journal of Pharmacology discloses that shea butter (karite) is known to relieve inflammation in the nostrils.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zabotto et al cited above, in view of GB 932662.

As set forth above, Zabotto et al discloses a topical composition containing karite oil. Zabotto et al teach the instant components such as lupeol, amyrin, and butyrospermol are natural unsaponifiable components of karite oil (Note col. 2)

Zabotto et al do not disclose the composition in an oral dosage form.

GB 932662 teaches butyrospermol, amyrin, and parkeol in a oral form (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Zabotto et al and GB 932662, since GB 932662 teaches karite extract (butyrospermol) in an oral form and Zabotto et al teaches the properties of karite oil. Depending on the symptoms and area to be treated, one would be motivated to use an the appropriate dosage form.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zabotto et al cited above, in view of SU 1181171.

As set forth, Zabotto et al discloses topical compositions containing karate oil.

Zabotto et al do not teach Calendula officinalis in the composition.

SU 1181171 teaches the anti-inflammatory properties of the marigold plant and its extract (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add marigold extract in Zabotto et al's composition. One would be motivated to do so with a reasonable expectation of at least an additive if not a synergistic effect in the composition since Zabotto et al teaches karite oil as a general

skin protectant and notably a protectant against erythema, and SU 1181171 teaches the anti-inflammatory properties of marigold.

Claims 1-5, and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laur et al (5679393).

Laur et al teach a composition with shea butter fractions containing triterpene alcohols and sterols (col. 111, lines 40-51). Laur et al teach the composition in a topical emulsion form (Note examples). Laur et al disclose the unsaponifiable material from shea butter and other plants, have valuable properties for the fields of cosmetology, pharmacy, or medicine (col. 2, lines 29-33).

Laur et al do not teach the instant amount of lupeol, amyrin, sterols, and butyrospermol or the unsaponifiable material in an oral dosage form.

The concentration of the unsaponifiable material in the composition would have been obvious to one of ordinary skill in the art at the time the invention was made since the concentration depends on the nature and process of extraction. One would be motivated to do so since Laur et al provide the general guidelines for extraction of shea butter.

Further, is deemed obvious to one of ordinary skill in the art at the time the invention was made to provide the karite composition in a topical or systemic dosage form since dosage forms are known to a skilled practioner in the art. The dosage form depends on the area and symptoms to be treated, thus one would be motivated to use the appropriate dosage form according to the condition to be treated.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laur et al cited above, in view of WO 9922706.

As set forth above, Laur et al teach a composition containing shea butter fractions.

Laur et al do not specify preventing or treating inflammation using shea butter fractions.

WO 9922706 teaches Butyrospermum parkii as a dermatological, anti-inflammatory, and vulnerary compound. (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Laur et al's composition containing shea butter fractions to prevent or treat inflammation since WO 9922706 teaches Butyrospermum parkii anti-inflammatory properties.

Correspondence

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:30pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

2/4/02

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER

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